



Navigating the Center for Drug Evaluation and Research: What You Should Know for Effective Engagement



March 31st, 2016

8:00 a.m. **Registration**

8:30 a.m. **Introduction and Opening Remarks**

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, FDA
John Whyte, MD MPH, Director, Professional Affairs and Stakeholder Engagement, FDA

SESSION ONE: BUILDING BLOCKS OF ENGAGEMENT...WHEN, WHY, AND HOW

8:45 a.m. **Can You Hear Me Now? *The Importance of Patient Engagement***

John Whyte, MD MPH, Director, Professional Affairs and Stakeholder Engagement, FDA

9:00 a.m. **An NDA at the FDA *Understanding the Drug Approval Processes***

Hank Hoang, PharmD, Pharmacist, Professional Affairs and Stakeholder Engagement, FDA

9:30 a.m. **Engagement with the FDA**

Richard A. Moscicki, MD, Deputy Center Director for Science Operations, FDA

9:55 a.m. **FDA's Patient-Focused Drug Development**

Pujita Vaidya, MPH, Operations Research Analyst, Office of Strategic Programs, FDA

10:25 a.m. **Break**

10:40 a.m. **Drug Availability *Shortages and Demand***

CAPT Valerie Jensen, RPh, Associate Director of Drug Shortage Staff, FDA

11:00 a.m. **Generic Drugs *Busting the Myths***

CAPT Jason Woo, MD MPH FACOG, Senior Medical Officer, Office of Generic Drugs, FDA

11:30 a.m. **Lunch**

1:00 p.m. **Jeopardy *Let's Play Jeopardy***

SESSION TWO – ENGAGEMENT...PUTTING THE PIECES TOGETHER

1:30 p.m. **Making Sure My Meds Are Safe *Manufacturers and Quality Controls***

Brian Hasselbalch, Deputy Director, Office of Policy for Pharmaceutical Quality, FDA

1:55 p.m. **The Small Print *Reporting Side Effects***

CAPT Catherine Chew, PharmD, Deputy Director, Division of Drug Information, FDA

2:20 p.m. **ABC's of OTC's *Little-Known Facts about Over-the-Counter Drugs***

Karen Mahoney, MD, Deputy Director, Division of Nonprescription Drug Products, FDA

2:45 p.m. **Break**

3:00 p.m. **Learn from the Pros *Stories of Engagement from Advocacy Groups***

Cynthia A. Bens, Vice President of Public Policy, Alliance for Aging Research
Bernadette O'Donoghue, Executive Director, Leukemia & Lymphoma Society

3:40 p.m. **Final Words of Wisdom**

John Whyte, MD MPH, Director, Professional Affairs and Stakeholder Engagement, FDA